AD_____

Award Number: DAMD17-99-1-9044

TITLE: Prostate Cancer Screening Efficacy in African-Americans Using Case-Control Methodology

PRINCIPAL INVESTIGATOR: Paul A. Godley, M.D., Ph.D.

CONTRACTING ORGANIZATION: The University of North Carolina at Chapel Hill
Chapel Hill, North Carolina 27599-1350

REPORT DATE: July 1999

TYPE OF REPORT: Final

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 074-0188

1. AGENCY USE ONLY (Leave blank)	2. REPORT DATE	3. REPORT TYPE AND DATES COVERED
	July 1999	Final (1 Jan 99 - 30 Jun 99)

4. TITLE AND SUBTITLE
Prostate Cancer Screening Efficacy in African-Americans Using Case-Control Methodology

5. FUNDING NUMBERS
DAMD17-99-1-9044

6. AUTHOR(S)
Paul A. Godley, M.D., Ph.D.

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
The University of North Carolina at Chapel Hill
Chapel Hill, North Carolina 27599-1350

E-MAIL:
PGODLEY@MED.UNC.EDU

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)
U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

10. SPONSORING / MONITORING AGENCY REPORT NUMBER

11. SUPPLEMENTARY NOTES

12a. DISTRIBUTION / AVAILABILITY STATEMENT
Approved for public release; distribution unlimited

12b. DISTRIBUTION CODE

13. ABSTRACT ***(Maximum 200 Words)***

The purpose of this project was to conduct a pilot study that would generate supporting information regarding medical record documentation of genito-urinary symptoms for a population-based case-control study of PSA screening for prostate cancer in African Americans. The lack of symptoms documented in the patient's medical record was to be used as evidence that PSA was intended as a screening examination. The database of patients screened with PSA at UNC Hospitals was reviewed and we began a preparatory analysis of available patients. We identified the number of patients to be abstracted and generated a report detailing patient name, date of test, test value, and the patient's medical record number through the collaboration of UNC Hospitals and the UNC School of Medicine Office of Information Services. We had numerous consultations with a biostatistician regarding appropriate statistical techniques to compare blinded coding of PSA test (diagnostic vs. screening) with the intentions of the ordering physician. Although UNC's Institutional Review Board approved the pilot study on January 11, 1999 after acknowledging the minimal risk associated with the project, we were unable to execute the pilot due to the six month time constraint and lack of approval from the Army's Human Subjects Research Review Board. In the future, we do plan to conduct the study and use the results as support for a case-control screening proposal with the collaborative efforts of Dr. Noel Weiss.

14. SUBJECT TERMS
Prostate Cancer, Prevention, Screening, PSA, Epidemiology, and Health Services Research

15. NUMBER OF PAGES
7

16. PRICE CODE

17. SECURITY CLASSIFICATION OF REPORT	18. SECURITY CLASSIFICATION OF THIS PAGE	19. SECURITY CLASSIFICATION OF ABSTRACT	20. LIMITATION OF ABSTRACT
Unclassified	Unclassified	Unclassified	Unlimited

NSN 7540-01-280-5500

Standard Form 298 (Rev. 2-89)
Prescribed by ANSI Std. Z39-18
298-102

FOREWORD

Opinions, interpretations, conclusions and recommendations are those of the author and are not necessarily endorsed by the U.S. Army.

___ Where copyrighted material is quoted, permission has been obtained to use such material.

___ Where material from documents designated for limited distribution is quoted, permission has been obtained to use the material.

___ Citations of commercial organizations and trade names in this report do not constitute an official Department of Army endorsement or approval of the products or services of these organizations.

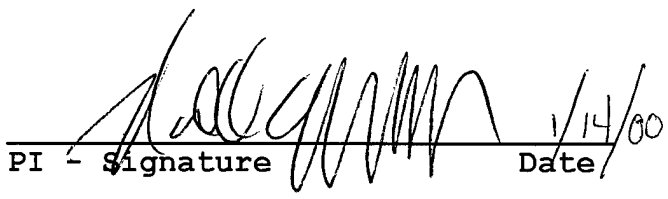
N/A In conducting research using animals, the investigator(s) adhered to the "Guide for the Care and Use of Laboratory Animals," prepared by the Committee on Care and use of Laboratory Animals of the Institute of Laboratory Resources, national Research Council (NIH Publication No. 86-23, Revised 1985).

N/A For the protection of human subjects, the investigator(s) adhered to policies of applicable Federal Law 45 CFR 46.

N/A In conducting research utilizing recombinant DNA technology, the investigator(s) adhered to current guidelines promulgated by the National Institutes of Health.

N/A In the conduct of research utilizing recombinant DNA, the investigator(s) adhered to the NIH Guidelines for Research Involving Recombinant DNA Molecules.

N/A In the conduct of research involving hazardous organisms, the investigator(s) adhered to the CDC-NIH Guide for Biosafety in Microbiological and Biomedical Laboratories.



PI - Signature Date 1/14/00

TABLE OF CONTENTS

INTRODUCTION:

Of the screening tests for early prostate cancer, only the PSA blood test stands out as both convenient to administer and potentially sensitive enough to detect prostate cancer while it is localized to the prostate. The purpose of this project was to conduct a pilot study that would generate supporting information regarding medical record documentation of genito-urinary symptoms for a population-based case-control study of PSA screening for prostate cancer in African Americans. Archived PSA data from the UNC database containing laboratory test results was used to determine which patients without the diagnosis of prostate cancer had a PSA test performed and whether this test was ordered for diagnostic or screening purposes.

BODY:

Phase I of the project began in January 1999, and consisted of collaborations between Dr. Paul Godley and the established case-control investigator Dr. Noel Weiss. These interactions took place on numerous occasions via phone contact and e-mail correspondence and led to a better understanding of the design and analysis of case-control studies of screening. Dr. Paul Godley continued his independent study through directed readings on research technique throughout the initial phase of this project.

During this time period, plans for the pilot study were refined. Questionnaires were designed and developed to be used by both the raters and the attending physician responsible for ordering the PSA test. These questionnaires were similar in content for the purpose of increasing the concordance rate among physicians. Four physicians from various specialties including a medical resident, oncologist, urologist, and medicine attending were chosen to evaluate medical record content to determine the intent of the PSA test ordered by the patient's physician.

The database of patients screened with PSA at UNC Hospitals was reviewed and we began a preparatory analysis of available patients. Merging a file of known cases from the UNC Hospitals tumor registry with the database of laboratory test results at UNC decreased the number of known prostate cancer patients in the data set. This step did not remove all patients with prostate cancer, but it improved the efficiency of the subsequent medical records search. Although UNC's Institutional Review Board approved the pilot study on January 11, 1999 after acknowledging the minimal risk associated with the project, we were unable to execute the pilot due to the six month time constraint and lack of approval from the Army's Human Subjects Research Review Board.

Phase II of the project included the gathering of information. We identified the number of patients to be abstracted and generated a report detailing patient name, date of test, test value, and the patient's medical record number through the collaboration of UNC Hospitals and the UNC School of Medicine Office of Information Services. In the future, we plan to use lack of symptoms documented in the patient's medical record as evidence

that PSA was intended as a screening examination. The four physicians and ordering physician involved in the patient's record evaluation will complete questionnaires using standardized criteria. After reviewing the patient charts, we plan to exclude patients with a pre-existing prostate cancer diagnosis.

To further project development, we had numerous consultations with a biostatistician regarding appropriate statistical techniques to compare blinded coding of PSA test (diagnostic vs. screening) with the intentions of the ordering physician. It was decided we should evaluate the data using concordance rates although there is potential complication due to the variety of specialties among the physicians. The data will be assessed using the kappa statistic with the hope that kappa exceeds 60%.

Due to our inability to execute the pilot study, we were unable to consolidate and evaluate the information obtained during Phase II. We do plan to conduct the study and use the results as support for a case-control screening proposal with the collaborative efforts of Dr. Noel Weiss.

KEY RESEARCH ACCOMPLISHMENTS:

We laid the groundwork for a pilot study of retrospective review of medical records to assess reasons for ordering PSA blood tests.

REPORTABLE OUTCOMES:

Funding was applied for based on work supported by this award.

CONCLUSIONS:

This award enabled us to lay the groundwork for a pilot study to support the development of a case-control study of prostate cancer screening efficacy in African Americans. During the allotted time period we were able to consult with our biostatistician and investigate the availability of archived PSA data. In the future, more research could be accomplished by extending the funding period.

REFERENCES:

None

APPENDICES:

None

LIST OF STUDY PERSONNEL:

Paul A. Godley, MD, PhD	Principal Investigator
Noel Weiss, MD, DrPH	Consultant
Ashutosh Kshirsagar	Research Assistant